

Docket No. 040A.0001U1(US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : GROSS
 Serial No. : 09/338,729
 Filing Date : June 23, 1999
 For : COMPOSITION AND METHOD FOR TREATING SKIN
 Examiner : L. Wells
 Group Art Unit : 1617

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

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 on
 Date: Oct. 7, 2003

Signature: Christine Wilkes Bermant
 Christine Wilkes Bermant (Reg. No. 37,967)

DECLARATION UNDER 37 C.F.R. 1.132

I, Dennis Gross, M.D. declare that:

1. I am currently a dermatologist, having an office at 105 East 37th Street, New York, New York. In this capacity, I treat numerous patients with varying skin conditions, and have been in practice for over 12 years. I am experienced in areas such as cosmetic dermatology (e.g. chemical peels, hair transplantation, dermabrasion, collagen injections, vein sclerotherapy), dermatologic surgery (e.g. skin cancer surgery and laser surgery) and general dermatology (e.g.

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skin cancers, cutaneous allergy, hair disorders, nail disorders, psoriasis, blistering disorders, connective-tissue diseases, photomedicine, cutaneous lymphoma).

2. My educational background includes: Bachelors degree, *magna cum laude*, from Wesleyan University (1980), major: biology/psychology, and M.D., State University of New York at Stony Brook (1986) where I was awarded Research Distinction Award, Lemberg Foundation Grant, and Scholarship Award for cancer research by a medical student. I completed postundergraduate biomedical research (1981-1982) at Rockefeller University where I was awarded Wesleyan University Postgraduate Research Fellowship. I completed my internal medicine internship (1986-1987) at Albert Einstein College of Medicine/Montefiore Medical Center and have Board Certification for General Medicine. I also completed my residency (1987-1990) at New York University Medical Center, Department of Dermatology/Skin and Cancer Unit.

3. I am the inventor for U.S. application serial number 09/338,729 and have read and understand this patent application. I am also familiar with the outstanding non-final Office Action of July 8, 2003 in the captioned case.

4. In the non-final Office Action of July 8, 2003, the Patent Office contends that no criticality is seen in the particular order of application of the claimed first and second dermatological compositions. It is respectfully submitted that the claimed, sequential order of application of the first and second dermatological compositions is necessary to achieve the desired benefits of the claimed method as opposed to a reverse order application, as explained herein.

5. As supported by U.S. application serial number 09/338,729 at page 9, the pH of the formulation is an important factor in the ability of the formulation to safely neutralize the formulation of Step 1. A high pH is necessary because it is believed that the rapid fluctuation in pH is responsible for many of the benefits of the claimed invention, for example, allowing beneficial effects to occur without the need for harsh peeling of the outer layers of the skin.

6. All of the combined benefits of the presently claimed method would not be achieved if the sequential order of application of the claimed first composition to the claimed second composition was reversed because the skin would then never be exposed to the non-neutralized acid in its non-conjugated, stronger form. For example, the acids employed in the first compositions are significantly effective in exerting their dermatological benefit when applied to the skin in their non-neutralized form and maintained in this form for a period of time on skin. Once the acid of the first composition is neutralized by the second composition including its alkaline agent, the chemical structure of the non-neutralized acid is immediately altered as the acid is converted into the conjugated salt form, which is less potent than the non-neutralized acid. Further, the acid salt can advantageously and beneficially remain on the skin, without requiring removal.

Moreover, application of the claimed second composition, including its alkaline agent, directly to the skin as a first step would not itself confer the benefits set forth below in paragraph 8. Nor would these benefits even be achieved by then applying the claimed first composition after the claimed second composition. That is, if the claimed second composition was applied directly to the skin prior to the first claimed composition, then the acid component would be applied to the skin after neutralizing ingredients were already present on the skin. This would immediately transform the acids to their salt-form conjugates, making them less potent, and thus the non-neutralized, stronger acid would not have the opportunity to itself penetrate the skin.

The initial exposure of the skin to the first composition including its non-neutralized stronger acid, followed by neutralization with the second composition is a necessary sequential step in the claimed process for the desired mechanism of action and advantageous results achieved by the invention.

7. A particular advantage of the claimed invention is that following application of the first and second compositions, moisturizer, sunscreen and/or makeup may be applied as usual. For instance, as described in the method of use example set forth at page 11 of U.S. application serial number 09/338,729, preferably, the skin is washed prior to application of the first step of the peel. The formulation of step 1 is applied all over the area of the skin to be treated, preferably in a circular motion, and allowed to dry for approximately 3 minutes. The formulation of step 2 is

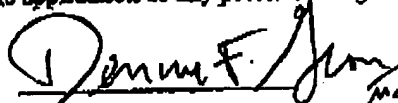
then applied in the same manner and allowed to dry completely. After step 2 is dried, moisturizer, sunscreen and/or makeup may be applied as usual. Neither formulation should be rinsed off of the skin.

8. Moreover, in addition to the above and as further supported by my U.S. application serial number 09/338,729 at page 11, last paragraph to page 12, as a result of a rapid change in pH when the composition of Step 1 is neutralized by the composition of Step 2, there is an increase in vasopermeability causing slight edema in the skin, which helps to reduce the appearance of lines and give the skin a healthy appearance. This may be caused by the warmth generated by the exothermic reaction that occurs when the composition of Step 2 reacts with the composition of Step 1 on the skin. Advantageously, the neutralization step potentiates the anti-aging and anti-acne effects of the acid step, which are further potentiated by the ability of the consumer to use the present invention as often as once a day, and by the conversion of the acid(s) to their non-irritating salt forms, which are also dermatologically active. The claimed invention is useful in reducing the appearance of fine wrinkles and lines, reducing pore size, exfoliating the skin, eliminating acne, toning the skin, enhancing the skin's radiancy, and providing softer, smoother skin with a more uniform appearance.

9. I declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful and false statements so made are punishable by fine or imprisonment or both, under 18 USC 1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

10/7/03


Dennis Gross, M.D.